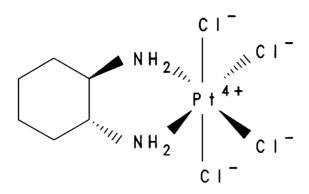
TETRAPLATIN

NSC - 363812



Chemical Name: Platinum, tetrachloro(1,2-cyclohexane-diamine-N,N')-, (OC-6-22-(trans))-

Other Names: U-77,233, Ormaplatin (USAN)

CAS Registry Number: 62816-98-2

Molecular Formula: $C_6H_{14}Cl_4N_2Pt$ M.W.: 451.1

How Supplied: For injection, 50 mg, vial: supplied as a sterile freeze-dried product containing 50 mg of tetraplatin, 500 mg of mannitol, USP, and 90 mg of sodium chloride, USP in a 20 mL amber vial.

Solution Preparation: 50 mg/vial: Constitute with 10 mL of Water for Injection, USP. Each milliliter of resulting solution contains 5 mg of tetraplatin with 50 mg of mannitol, USP, and 9 mg of sodium chloride, USP, at a pH of 3.5 to 5.5.

Storage: Store the intact vials under refrigeration (2-8°C).

Stability: Shelf-life surveillance of the intact vials is ongoing. One lot was stable for at least four years at room temperature (22-25 °C). This lot was stable for at least one year at elevated temperature (50 °C).

CAUTION: This single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

Reference:

1. Cheung YW, Cradock JC, Vishnuvajjala BR, and Flora, KP: Stability of cisplatin, iproplatin, carboplatin, and tetraplatin in commonly used intravenous solutions, Am J Hosp Pharm 44:124-130, 1987.